



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 10, 2017

Lucid, Inc.
c/o Mr. James Joy
Quality Assurance and Regulatory Manager
2320 Brighton Henrietta Town Line Road
Rochester, New York 14623

Re: K080788

Trade/Device Name: VivaScope® System
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: PSN
Dated: September 5, 2008
Received: September 8, 2008

Dear Mr. Joy:

This letter corrects our substantially equivalent letter of September 17, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.

Director

Division of Surgical Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: VivaScope® System

Indications for Use:


The VivaScope® System is intended to acquire, store, retrieve, display and transfer in vivo images of tissue, including blood, collagen and pigment, in exposed unstained epithelium and the supporting stroma for review by physicians to assist in forming a clinical judgment.

Prescription Use X
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number 108675R

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K080788

510(k) Summary

Submitter: Lucid, Inc.
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Contact: James Joy
Quality Assurance Manager
Telephone (585) 239-9800
Fax (585) 239-9806

Date Prepared: March 17, 2008

Proprietary Name: VivaScope® System

Common Name: In vivo confocal reflectance microscope

Classification Name: Light, Surgical, Floor Standing (21 CFR 878.4580, Product Code FSS)

510(k) Numbers and Product Codes of Equivalent Devices

MicroDERM®
510(k) Number: K040171
Product Code: FSS
CFR Section: 878.4580
Visiomed AG, Ft. Lauderdale, FL

SiaScope II
510(k) Number: K023729
Product Code: FSS
CFR Section: 878.4580
Astron Clinica, Ltd., Crofton, MD

Intended Use

The VivaScope® System is intended to acquire, store, retrieve, display and transfer in vivo images of tissue, including blood, collagen and pigment, in exposed unstained epithelium and the supporting stroma for review by physicians to assist in forming a clinical judgment.

Device Description

The VivaScope® System is a reflectance confocal microscope, full color macroscopic imager, and software that captures images of in vivo tissue specimens from the exposed surface of the tissue, through the unstained epithelium and into the superficial supporting stroma. It provides non-invasive in vivo images of the epithelium and supporting stroma. The VivaScope® System does **NOT** provide automated analysis or diagnosis of the images it produces. It is capable of imaging cells in the epidermis of skin and the fibrous tissue (primarily collagen and fibrin) in the dermis. In addition, it is possible to visualize circulation of blood cells (including both erythrocytes and leukocytes) in capillaries and other small vessels.

The VivaScope® System produces horizontal sections of the skin using safe, low power infrared laser light at nominal wavelength of 830 nm (CDRH laser Class I). Horizontal sections make it straightforward to view the various layers of the skin in sequence, from the outer surface of the stratum corneum, through the granular, spinous and basal layers, to the level of the superficial reticular dermis.

The VivaScope® System produces high resolution images of the skin using confocal laser scanning microscopy. The key feature of confocal microscopy is the ability to produce in-focus images of thick specimens called "optical sectioning". The system is able to accomplish this by having the point source laser light, the illuminated spot in the sample, and the pinhole all lie in optically conjugate focal planes. The size of the pinhole (located in front of the photodiode) is matched to the size of the illuminated spot to reject out of focus light allowing for imaging of thin optical sections.

The VivaScope® System can image, display, store, retrieve, import and export in vivo confocal and macroscopic color images using the VivaScan® operating software and supporting PC hardware. Images are saved and stored using standard lossless image compression algorithms. Images are communicated to other devices using DICOM standard functionality that is incorporated into the VivaScan® operating software.

The VivaScope® System is comprised of four (4) major functional components: an imager, a display, a PC and a cart. A VivaScope® System will have either a VivaScope® arm mounted imaging head or a VivaScope® handheld imaging head, or both, and optionally, a VivaCam® full color macroscopic imaging head.

Conclusion

The VivaScope® System has the same intended use as its predicates and similar indication. All of the devices provide in vivo images of the skin for physician diagnostic review and referral purposes, and are capable of imaging the skin's components, including pigment, blood and/or collagen.

Additionally, the VivaScope® System's technological characteristics are very similar to the predicates, except for the light source. The VivaScope® System has the same major functional components as the predicates, i.e., imager, display, computer and cart, and uses the same operating principle, i.e., reflected light, to capture images of the skin. It also has the same technological capabilities in that it is capable of acquiring, storing, displaying and transmitting images.

The main difference in technology relates to the light source: the VivaScope® System uses laser as its light source and the predicate devices use LEDs. This difference, however, does not raise new types of safety or effectiveness questions, because the laser allows the VivaScope® System, like its predicates, to produce detailed images of the skin and its energy output is within the range of its predicates and complies with the FDA's safety requirements. Further, the VivaScope® System conforms to the same FDA and internationally recognized safety standards as the predicates.

For the forgoing reasons, the VivaScope® System is substantially equivalent to the predicate devices.